



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Advancing the Development of Pediatric Therapeutics: Pediatric Bone Health; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Pediatric and Maternal Health Staff in the Center for Drug Evaluation and Research and the Office of Pediatric Therapeutics are announcing a 1-day public workshop entitled "Advancing the Development of Pediatric Therapeutics (ADEPT): Pediatric Bone Health." The purpose of this initial workshop is to provide a forum to consider issues related to advancing pediatric regulatory science in the evaluation of bone health in pediatric patients.

Date and Time: The public workshop will be held on March 4, 2014, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held in the Pooks Hill Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814. The hotel's telephone number is 301-897-9400.

Contact: Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1732, FAX: 301-796-9858, email: denise.picabranco@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

FDA has engaged experts in pediatrics to address challenging issues related to the evaluation of effects on bone health for products used to treat pediatric patients. Identification of

signals in animal studies and adult clinical trials that warrant further clinical investigation and identification of biomarkers that may be predictive of bone health in children will be discussed. Additionally, strategies and methods to address the challenges of assessing long-term bone health for products used to treat pediatric patients will be discussed.

I. Participation in the Public Workshop:

There is no fee to attend the public workshop, but attendees should register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at PediatricBoneHealth@fda.hhs.gov before February 28, 2014. For those without Internet access, please contact Denise Pica-Branco (see Contact) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Denise Pica-Branco (see Contact) at least 7 days in advance.

II. Transcripts

Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and at <http://www.regulations.gov> approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301-827-9267.

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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